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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Iandiorio & Teska
260 Bear Hill Road
Waltham, MA 02451-1018

EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,053

Applicant(s)

HOUSTON ET AL.

Examiner

William H. Beisner

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-14 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/20/04.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 20 Jan. 2004 has been considered and made of record.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1744

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 and 4-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willner et al.(WO 98/40739) in view of Hoberman (US 4,889,992) and Fraatz et al.(US 5,372,936).

With respect to claim 1, the reference of Willner et al. discloses a cell biosensor device that includes a vessel for holding a sample to be tested in a medium comprising: a bio-sensor, in the vessel in the culture medium with the sample having a coating for attracting at least one pathogen expected in the sample; and a detection circuit responsive to the bio-sensor for indicating the presence of a pathogen on the bio-sensor (See page 5, line 1 to page 6, line 14; page 15, lines 15-25).

While the reference of Willner et al. discloses the use of a vessel for holding the sample to be contacted with the biosensor device, the reference does not specifically recite that the biosensor is sealed within the vessel.

The reference of Willner et al. discloses that the liquid phase biosensor allows for "stationary and flow analysis of aqueous samples" (See page 4, lines 2-3).

The reference of Hoberman discloses that it is desirable to maintain a culture vessel sealed while performing an assay to detect the presence of microorganism so as to prevent cross-contamination that is associated with sampling the culture vessels for analysis of the contents (See column 2, lines 37-68).

Art Unit: 1744

The reference of Fraatz et al. discloses that it is known in the art to provide a sensing device within a sealed culture vessel so as to avoid cross-contamination (See column 2, lines 16-47).

In view of these teachings, it would have been obvious to one of ordinary skill in the art to provide the biosensor device of the primary reference within a sealed vessel for the known and expected result of preventing and/or minimizing contamination of the sample during the analysis procedure.

With respect to claims 4, 6-14, the detection circuit operates by driving the biosensor at a predetermined resonant frequency and detecting shifts in the resonant frequency of the biosensor in response to attached pathogens. The detection circuit is continuously driven and instantaneously detects shifts as evidenced by the disclosure on page 17, line 28 to page 18, line 4, which states that "frequency changes can be monitored as a function of time".

With respect to claim 5, the detection circuit is external to the sample holding vessel (See page 15, lines 15-25).

6. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willner et al. (WO 98/40739) in view of Hoberman (US 4,889,992) and Fraatz et al. (US 5,372,936) taken further in view of Karube et al. (EP 0 215 669).

The combination of the references of Willner et al., Hoberman and Fraatz et al. has been discussed above.

Claims 2 and 3 differ by reciting that the biosensor for pathogen detection includes an array of biosensor elements with different coatings for attracting pathogens.

The reference of Karube et al. discloses that it is known in the art to provide an array of biosensor elements with respect to a single sensor device so as to simultaneously analyze a plurality of different analytes or pathogens (See page 7, lines 4-11, and Figure 16).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the primary reference so as to include an array of biosensor elements as suggested by the reference of Karube et al. for the known and expected result of providing a means recognized in the art for detecting a plurality of pathogens within a single sample.

Response to Arguments

7. Applicant's arguments filed 20 Jan. 2004 have been fully considered but they are not persuasive.

With respect to the rejection of the claims under 35 USC 102 over the reference of Willner et al., Applicant argue that the invention now includes a "sealed" vessel. Applicants argue that the reference of Willner et al. does not disclose the use of a "sealed" vessel and requires that additional agents are required during the operation of the system of Willner et al. which place the system of Willner et al. at risk with respect to contamination while the instant invention is self-contained and sealed and thus can continuously monitor for the presence of pathogens.

Applicants' comments are persuasive to overcome the 35 USC 102 rejection of record in view of the new language added to the claim that limits the device to a "sealed" vessel. However, this new claim language is not enough to patentably distinguish the instant claims over

Art Unit: 1744

the prior art of record. Specifically, the new ground of rejection under 35 USC 103 over the references of Willner et al. and the references of Hoberman and Fraatz et al. renders obvious the instantly claimed invention. Note, the reference of Willner et al. clearly discloses that the disclosed device can be used in either a stationary or flow analysis of aqueous samples (See page 4, lines 1-5). Also, while the reference of Willner et al. discloses the use of sensitivity increasing agents ("sensitivity increasing agents may be used"), the reference does not required their use. One of ordinary skill in the art would recognize that their use would not always be required when detecting larger concentrations of pathogens. Additionally, the instant claim language does not preclude the use of adding additional agents or removal of samples since as disclosed in the reference of Fraatz et al. a "sealed" vessel does not preclude adding or removing samples (See Figure 4). With respect to Applicants' comments concerning the steps disclosed by Willner et al. for detecting multiple cell types, the instant claims do not structurally preclude the performing of these steps since the vessel can be "sealed" with a rubber stopper as disclosed by the reference of Fraatz and would allow the addition of the reagents required for the detection steps of Willner et al. With respect to Applicants' comments contrasting the instant invention to the system of Willner et al.. while Applicants comment that the instant device allows "continuous" and "instantaneous" detection of pathogens, the instant claims are completely silent as to structure the would provide this continuous and instantaneous detection other than the vessel is "sealed". The instant claims merely recite a biosensor having a coating for attracting at least one pathogen, the biosensor "sealed" in the vessel and a detection circuit for indicating the presence of a pathogen.

With respect to the combination of the references of Willner et al. and Karube et al., Applicants argue that the reference of Karube et al. discloses a flow cell which is not "sealed" and requires the introduction of various agents which does not equate to continuous monitoring.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the reference of Karube et al. was cited as prior art that discloses the use of an array of biosensing elements with different coatings for detecting different pathogens. Applicants' comments are silent as to the combination of the references of Willner et al. and Karube et al. Applicant has merely argued the shortcomings of the reference of Karube et al.

For these reasons, the rejection of the claim over the references of Willner et al., Hoberman, Fraatz et al. and Karube et al. will be maintained.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1744

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB